REMARKS

Claims 1-10 are pending in the present application.

Rejections under 35 U.S.C. §102(b)/103

The Examiner maintains the rejection of claims 1-10 under 35 U.S.C. §102(b)/103 as being anticipated by or obvious over Pristoupil. In response to Applicant's arguments of September 23, 2002, the Examiner indicates that arguments are insufficient to distinguish the invention from Pristoupil. It appears that the position of the Examiner is that "chromatography" encompasses any separation of at least two components. Thus, the Examiner interprets the gross binding of protein to nitrocellulose to be a chromatographic separation from the low-molecular weight hydrophilic substances that migrate with the buffer front, as disclosed in Pristoupil.

Applicants traverse the rejection and withdrawal thereof is respectfully requested. The present invention, as encompassed by claim 1, is drawn to

> A chromatographic assay method, comprising the steps of:
> a) providing a polymeric membrane type flow matrix attached to a liquid-impervious backing, which flow matrix permits a capillary force assisted lateral flow therethrough, and at least a part of which flow matrix contains ion-exchange function **by the action of ion-exchange functional groups selected from the group consisting of diethyl aminoethyl (DEAE), trimethyl**

hydroxypropyl (QA), quaternary aminoethyl (QAE), quaternary aminomethyl (Q), diethyl-(2-hydroxypropyl)-aminoethyl, triethyl aminomethyl (TEAE), triethylaminopropyl (TEAP), polyethyleneimine (PEI), methacrylate, carboxymethyl (CM) orthophosphate (P), sulfonate (S), sulfoethyl (SE) and sulfoproyl (SP), wherein the flow matrix is a porous polymer material with pores in the range of 0.01-20μm;

b) treating the flow matrix to reduce or eliminate nonspecific adsorption properties of the flow matrix;

c) applying to the flow matrix a sample containing at least two components;

d) initiating a first lateral flow of aqueous fluid to transport the sample through the flow matrix and separate the components therein;

e) interrupting said lateral flow; and either

f1) detecting at least one of said separated components on the flow matrix in the position reached by the respective component when the flow was interrupted; or

f2a) initiating a second flow of aqueous fluid to transport the components in a direction substantially transverse to the direction of the first lateral flow;

f2b) interrupting said second lateral flow; and

f2c) detecting at least one of said separated components on the flow matrix in the position reached by the respective components when the second lateral flow was interrupted.

As noted above, the Examiner appears to interpret "chromatography" as encompassing any separation of at least two components. Thus, the Examiner interprets the gross binding of protein to nitrocellulose to be a chromatographic separation from the low-molecular weight hydrophilic substances that migrate with the buffer front, as disclosed in Pristoupil.

The present invention, as encompassed by amended claims 1 and 8, define the flow matrix as having at least a part which contains

ion-exchange function by the action of ion-exchange functional groups selected from the group consisting of diethyl aminoethyl (DEAE), trimethyl hydroxypropyl (QA), quaternary aminoethyl (QAE), quaternary aminomethyl (Q), diethyl-(2-hydroxypropyl)-aminoethyl, triethyl aminomethyl (TEAE), triethylaminopropyl (TEAP), polyethyleneimine (PEI), methacrylate, carboxymethyl (CM) orthophosphate (P), sulfonate (S), sulfoethyl (SE) and sulfoproyl (SP). There is no disclosure or suggestion of this feature in Pristoupil. As such, the present invention is neither anticipated by nor suggested over Pristoupil.

The Examiner relies on pages 115 and 116 of Pristoupil as teaching treatment of nitrocellulose to impart ion-exchange function. However, when the teachings of the reference are properly considered their entirety it is clear that Pristoupil teaches that under certain conditions there may be a very minor contribution of ionic forces in binding of the protein to the nitrocellulose, but that the major binding forces are the result of the interaction of the hydrophobic groups of the proteins with the dipoles of the nitrocellulose. Applicants note in this regard that Pristoupil teaches on page 115, 4th paragraph of Item 5, that the ion-exchange capacity of nitrocellulose corresponds to that of filter paper and is "rather low." Thus, any contribution from ion-exchange to the binding of the proteins in Pristoupil is minimal

and cannot be compared to the ion-exchange groups recited in amended claim 1, by which the present invention achieves full ion-exchange chromatography using nitrocellulose.

In addition, while Pristoupil disclose analyzing the ion-exchange capacity of the nitrocellulose, the reference further teaches treating the nitrocellulose to neutralize the already low ion-exchange capacity that is present. For example, page 115, Section 5, 2nd paragraph, states, "the negative charge of the membrane was markedly suppressed at acid pH values and also at neutral pH's, on membranes impregnated with Tween." In addition, page 123, Section 7 "Conclusion", "The impregnation of nitrocellulose membranes with neutral detergents hinders the adsorption of proteins which then migrate freely from the start during chromatography and can be easily separated into several fractions by electrophoresis." This principle is repeated on page 113, 5th full paragraph. Thus, Pristoupil teaches that nitrocellulose has a "rather low" natural ion-exchange capacity, which is to be negated by treating the membrane with neutral detergents. Thus, Pristoupil in no way suggests separation based on ion-exchange function, or ion-exchanges function based on recited functional groups of claims 1 and 8. The present invention is therefore in no way disclosed or suggested by the reference and withdrawal of the rejection is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, Ph.D. (Reg. No. 40,069) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

A marked-up version of amended claims and 8, showing all changes, is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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MARKED-UP VERSION SHOWING CHANGES

IN THE CLAIMS

Claims 1 and 8 have been amended as follows.

1. (Thrice Amended) A chromatographic assay method, comprising the steps of:

a) providing a polymeric membrane type flow matrix attached to a liquid-impervious backing, which flow matrix permits a capillary force assisted lateral flow therethrough, and at least a part of which flow matrix contains ion-exchange function **by the action of ion-exchange functional groups selected from the group consisting of diethyl aminoethyl (DEAE), trimethyl hydroxypropyl (QA), quaternary aminoethyl (QAE), quaternary aminomethyl (Q), diethyl-(2-hydroxypropyl)-aminoethyl, triethyl aminomethyl (TEAE), triethylaminopropyl (TEAP), polyethyleneimine (PEI), methacrylate, carboxymethyl (CM) orthophosphate (P), sulfonate (S), sulfoethyl (SE) and sulfoproyl (SP)**, wherein the flow matrix is a porous polymer material with pores in the range of 0.01-20μm;

b) treating the flow matrix to reduce or eliminate nonspecific adsorption properties of the flow matrix;

c) applying to the flow matrix a sample containing at least two components;

d) initiating a first lateral flow of aqueous fluid to transport the sample through the flow matrix and separate the components therein;

e) interrupting said lateral flow; and either

f1) detecting at least one of said separated components on the flow matrix in the position reached by the respective component when the flow was interrupted; or

f2a) initiating a second flow of aqueous fluid to transport the components in a direction substantially transverse to the direction of the first lateral flow;

f2b) interrupting said second lateral flow; and

f2c) detecting at least one of said separated components on the flow matrix in the position reached by the respective components when the second lateral flow was interrupted.

8. (Amended) A chromatographic device comprising a **polymeric** membrane type flow matrix attached to a liquid-impervious backing, which membrane permits a capillary force assisted lateral flow therethrough and ~~is modified to support ion exchange functions~~ **contains ion-exchange functional groups selected from the group consisting of diethyl aminoethyl (DEAE), trimethyl hydroxypropyl (QA), quaternary aminoethyl (QAE), quaternary aminomethyl (Q), diethyl-(2-hydroxypropyl)-aminoethyl, triethyl aminomethyl (TEAE),**

triethylaminopropyl (TEAP), polyethyleneimine (PEI), methacrylate, carboxymethyl (CM) orthophosphate (P), sulfonate (S), sulfoethyl (SE) and sulfoproyl (SP), wherein the flow matrix is a porous polymer material with pores in the range of 0.01-20μm.